

1 position is looking at how much testing can we do. And we  
2 are testing, and we are verifying. But we are up to 750  
3 tests a week right now and heading for more. We are a HACCP  
4 plant. We have our programs in place, our SOPs, our GMPs.  
5 And everything to me is pointing back to lot identification,  
6 isolating this pathogen as much as we can at the earliest  
7 stage in the process of this industry.

8           So my comment is I like what I am hearing. I  
9 certainly hope everyone else in this segment and the  
10 consumer groups here like what we are hearing and USDA likes  
11 what we are hearing. To isolate and get back to the  
12 carcass, and to get back to where we need to be with the  
13 proper kind of testing, and really look at a prevention  
14 HACCP program the way it was designed, is where we need to  
15 be and where we need to go.

16           On the non-intact issue, all I can say is we are a  
17 company that suddenly we are faced with many, many sub-  
18 primal cuts that come into our organization. They are  
19 already trimmed. But we are going to have to face something  
20 new again, once again, with the issues that are coming  
21 along. Again, it all points back to control and to  
22 prevention, and that is really where we need to be. HACCP  
23 is truly a prevention program when it is in its proper  
24 perspective. Thank you.

25           MR. BILLY: Thanks, Tony. Other questions or

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1     comments about the information presented by the folks from  
2     Kansas State University?

3             MR. MOSS: My name is Joe Moss. I am with JTM  
4     Provisions in Cincinnati, Ohio. I just want to add to what  
5     was just stated. Indeed, over the last several years, us  
6     grinders, everybody seems to keep pointing the finger to us  
7     to take care of this E. coli problem. To date, you know, I  
8     have worked on it a great deal. And I stand a lot of risk  
9     each day as to whether someone might get sick on something  
10    that I produce. That certainly would ruin my whole life's  
11    work.

12            I have studied hard to see how it is that I can  
13    make 0157 not be in my product, and I haven't come up with a  
14    solution. Indeed, if 0157 comes into my plant, there is  
15    really no way for me to get rid of it, since I make raw  
16    hamburgers. I certainly also would like to reiterate then  
17    as well that I particularly like what I am hearing today,  
18    that I have been really frustrated over the last several  
19    years of having the fingers pointing at me every day to say  
20    that I am the problem, as though there is something much  
21    that I can do about it.

22            The questions and answers that were submitted by  
23    FSIS prior to this meeting today actually continue to point  
24    at that, quite frankly. There were, you know, what if a  
25    receiving establishment finds 0157 in their product or in

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1 the meat that they receive, what should they do. And the  
2 answer was, well, reassess your HACCP plan, take corrective  
3 actions. Well, you know, again, I read something like that,  
4 and I go why do I reassess my HACCP plan, I didn't do  
5 anything. What corrective actions do I have available to  
6 me? I am not sure I have any.

7 So indeed, you know, the issue is a bit more of a  
8 carcass. If we are going to try to get rid of 0157 out of  
9 the food supply, continuing to try to point at the grinders  
10 seems illogical, that indeed if we are trying to get rid of  
11 0157 out of the food supply, that that would have to be  
12 something that would happen at the carcass level. Thanks.

13 MR. BILLY: Thanks. Any other -- okay. Tony, did  
14 you have any other points you wanted to make?

15 MR. DUGUAY: Excuse me?

16 MR. BILLY: Do you have any other points you would  
17 like to make?

18 MR. DUGUAY: Not really. Just that the non-intact  
19 issue, I think, again from what I am hearing on the research  
20 that has been done so far, I think that I would like to see  
21 us go back and reevaluate, and the agency consider the  
22 carcass testing program and the interventions and risk  
23 assessment that needs to be performed on both non-intact and  
24 the carcass sampling method that we are proposing this  
25 morning.

1           MR. BILLY: We will carefully consider all data,  
2   as I said in my opening remarks, all data and information  
3   that is made available. So you can be assured of that.

4           The next person on my list is -- oh, yeah, go  
5   ahead, Marty.

6           MR. HOLMES: Does that mean that you would re-look  
7   at your risk assessment that is being done now with Mark to  
8   consider intact steaks? I had understood at this point that  
9   it did not include intact steaks at all in the risk  
10  assessment -- non-intact steaks, excuse me.

11          MR. BILLY: Yeah. Our original plan for risk  
12  assessment was focused on ground beef. But we have  
13  reconsidered that, and we are looking at doing some  
14  additional work after we complete the initial planned risk  
15  assessment on ground beef to look at other beef products. I  
16  don't know if you want to add to that at all.

17          MR. HOLMES: Would that mean you would be willing  
18  to consider holding this policy clarification in abeyance on  
19  non-intact steaks until that risk assessment is done?

20          MR. BILLY: We are going to look at all of the  
21  data and information. We are not going to reach any  
22  conclusions at this public meeting. But we encourage that  
23  kind of data and information to inform us about decisions  
24  like that. Caroline.

25          MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center

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1 for Science in the Public Interest. I just wanted to add  
2 some data to what you are considering in terms of the other  
3 cuts of meat issue. In our review of 225 food borne illness  
4 outbreaks, we identified two outbreaks of E. coli 0157:H7  
5 linked to roast beef. One was in 1990, July 1990. The  
6 second was in August 1995. And we can't tell you whether  
7 those products were needle tenderized or not.

8 In addition, we believe CDC would have better  
9 information related to outbreaks linked to meats -- of  
10 0157:H7 linked to meats other than ground beef. But there  
11 are some outbreaks which occur. And clearly, the issue is  
12 whether the needle tenderizing or some other step may have  
13 contributed to that.

14 MR. BILLY: Marty.

15 MR. HOLMES: Marty Holmes from North American Meat  
16 Processors. I would like to follow up that we did approach  
17 CDC to ask them if they had any data, and they said they do  
18 not, on mechanically tenderized products associated with  
19 illnesses from 0157:H7. We tried to find that data.

20 MR. BILLY: All right. The next presenter is  
21 Richard Wood. Is he here?

22 (Pause)

23 MR. BILLY: As I say, going, going, gone. All  
24 right. Heather.

25 MS. KLINKHAMER: Heather Klinkhamer with Safe

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## AFTERNOON SESSION

(1:35 p.m.)

3 MR. BILLY: Are you ready, Phil? Please be  
4 seated. I would like to get started. I understand that  
5 there are some additional questions that a couple of people  
6 have thought about over lunch in terms of the proposal. But  
7 to be fair to the other presenters, what I would like to do  
8 is to work through the rest of the list, and then at the  
9 end, we'll come back. And if there are other thoughts about  
10 the proposal that the industry coalition put on the table,  
11 we can deal with them at that time.

12           The next person on my list is Phil Olsson with  
13   Olsson, Frank & Weeda, and he is representing Food Maker.  
14   Phil.

15 MR. OLSSON: Thank you very much. I'm appearing  
16 here today to present a statement for Dr. Dave Theeno of  
17 Food Maker and Jack-in-the-Box. Dave Theeno and Food Maker  
18 have been leaders in the area of sampling and testing for E.  
19 coli, a leader in the quick service restaurant field, and he  
20 regretted very much that he could not be here today, and he  
21 asked me if I would present his statement. And I am pleased  
22 to do that.

23           As most of you are aware, Jack-in-the-Box has been  
24   actively doing E. coli 0157:H7 testing since February of  
25   1993. The testing program has been run in partnership with

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1 the company's hamburger patty suppliers. Jack-in-the-Box  
2 considers it a critical element in its overall food safety  
3 system. It must be clearly stated at the outset that no  
4 technique and/or amount of 0157:H7 testing can ensure that  
5 uncooked ground beef is absolutely free of the organism.  
6 However, the Jack-in-the-Box 0157 testing program has  
7 successively enabled the company to select vendors that are  
8 doing a superior job of controlling microbial contamination  
9 in the slaughter and fabrication process.

10 The Jack-in-the-Box 0157 testing program was  
11 recently reviewed by outside experts and found to be  
12 statistically effective at detecting 0157:H7 contamination  
13 levels in ground beef. Jack-in-the-Box has also been in  
14 communication with other companies involved with sampling  
15 programs and believes that these other programs are  
16 effective for their intended uses.

17 The 0157 problem cannot and will not be solved by  
18 individual efforts. Jack-in-the-Box would not have been  
19 able to achieve its current levels of control had the  
20 company not had working partnerships with its suppliers.  
21 The only way that the entire food system or any members of  
22 it will make improvements is by working together. To that  
23 end, several initiatives are underway or soon shall be that  
24 will have a significant positive impact on the control of  
25 0157, in the opinion of Jack-in-the-Box.

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1           First, a working consortium within the beef  
2 industry is proposing initiation of carcass 0157 testing as  
3 a verification procedure for in-plant interventions. Since  
4 the introduction of the organism to the edible food supply  
5 occurs in the transformation from live animals to food, this  
6 is the proper place to focus efforts. There will  
7 undoubtedly be debate over sampling techniques and  
8 frequency. However, those issues can be addressed as we go.  
9 This initiative deserves the agency's support.

10           Secondly, the beef industry consortium supports  
11 doing a pilot study in conjunction with a consortium of  
12 quick service restaurant operators which will assess the  
13 efficacy of the in-plant intervention and investigate  
14 enhanced sample acquisition and analytical technologies.  
15 These two initiatives will require six to nine months to  
16 complete and perform the proper assessment of the results.

17           USDA FSIS has a risk assessment underway which  
18 will further help define how we may all collectively better  
19 focus our efforts to control the threat posed by 0157.  
20 During the period of time required to evaluate this  
21 proposal, Jack-in-the-Box will continue its current testing  
22 program. It is Jack-in-the-Box's understanding that its  
23 counterparts in the food service industry will also continue  
24 their current testing programs. During this time, it is  
25 imperative that the existing discretionary lotting system

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1 Tables Our Priority. I want to begin by thanking FSIS for  
2 responding to STOP's May 1998 ground beef guidelines  
3 comments by addressing the contaminated intact products  
4 intended to be processed in a manner that would introduce  
5 surface contamination to the interior of the product. This  
6 was the right thing to do to protect public health, and we  
7 strongly urge FSIS to implement the new policy as soon as  
8 possible. Consumers are counting on you to enforce food  
9 safety laws and to enact policies that promote public health  
10 like this one.

11 Instead of giving you a presentation, I actually  
12 have a list of questions to ask you. Some of these are for  
13 clarification on the directive and also about portions of  
14 the Q and A, if that is okay.

15 MR. BILLY: Mm-hmm.

16 MS. KLINKHAMER: I'll also just add that some of  
17 these questions arose from responses that I had gotten to a  
18 FOIA request regarding the E. coli 0157:H7 sampling program.  
19 The first question that I have is the definition of raw  
20 ground beef products in the directive 10010.1 version from  
21 February of '98. It describes products that may be  
22 distributed to consumers as such. And I wondered what you  
23 meant by that.

24 DR. ENGELJOHN: This is Dan Engeljohn with FSIS.  
25 The products affected by that directive for raw ground beef

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1 products were those that most likely would be purchased by a  
2 consumer, sold to a consumer as such. So manufacturing  
3 trimmings or boneless beef products that in and of  
4 themselves would not normally be sold in that form but would  
5 be formulated into ground beef to make a certain lean meat  
6 requirement, a certain fat content requirement, would in  
7 fact then not be sampled themselves, but the finished  
8 product would be. So it would be what normally would be  
9 available to the consumer.

10 I think we identified a number of products, such  
11 as products derived from advanced meat recovery, which  
12 normally in and of itself is not sold as ground beef.

13 MS. KLINKHAMER: Okay. Just a comment for you.  
14 And after I am finished analyzing the responses that I have  
15 gotten, I'll send a document to you. But I have noticed  
16 just by leafing through the returned documents that quite a  
17 few inspectors are not including samples in the sampling  
18 program because they say it is intended for retail, which  
19 seems -- it seems that they are implementing what is  
20 opposite of the intent here, so just for your information.

21 With regard to the section 4(b), No. 2, could you  
22 explain the excepted criteria to be exempt, so to speak? In  
23 No. 2, it says each lot is specific enough -- sorry. What  
24 amount of product is to be tested under No. 1, and how  
25 frequently should it be tested to meet the requirements in

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1 No. 1, B1?

2 DR. ENGELJOHN: I'm sorry, Heather, I can't  
3 remember what that section is.

4 MS. KLINKHAMER: Oh, I assumed you had a copy in  
5 front of you.

6 DR. ENGELJOHN: With section 1 --

7 MS. KLINKHAMER: It is under section 4(b)(1).

8 DR. ENGELJOHN: And that is the situation where  
9 samples are collected at inspected establishments, where  
10 they conduct routine daily testing.

11 MS. KLINKHAMER: Right.

12 DR. ENGELJOHN: We don't have defined what would  
13 be the minimum requirements for a sampling program.

14 (Pause)

15 MS. KLINKHAMER: Could you -- okay. Moving to  
16 No. 3 in the same section, could you tell me which  
17 interventions have been accepted under No. 3?

18 (Pause)

19 MS. GLAVIN: None of us is able to do it out of  
20 our memories, but we do have in the regs a list of  
21 interventions in the HACCP pathogen reduction reg, accepted  
22 interventions. And to the best of my memory, it includes  
23 steam vac and steam pasteurization, and I believe some other  
24 things, but I wouldn't go with my memory on that.

25 MS. KLINKHAMER: So it is interventions that are

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1 mentioned in the Federal Register notice on the pathogen  
2 reduction HACCP regulation. And to your knowledge, no new  
3 interventions have been adopted since?

4 MR. BILLY: I think they are not in that part of  
5 the regs. They are in a different part that lists approved  
6 or accepted process interventions. Can you come up? Speak  
7 in the microphone.

8 MS. NEIBRIEF: Judy Neibrief, FSIS. I agree. I  
9 am just not sure that they are in any regulation as opposed  
10 to preamble discussions of the work done so far and what  
11 people have been using in order to satisfy regulatory  
12 requirements. But without the reg book, I would hate to  
13 swear.

14 MS. KLINKHAMER: I have another question related  
15 to No. 3. I was wondering how prevention of the use of  
16 boneless beef or carcasses from outside sources is enforced.  
17 For instance, in mixing ground beef, I understand that  
18 sometimes a product like AMR is added as a constituent of  
19 the ground beef. Are those constituents part of this  
20 exemption, or would those be tested separately?

21 MS. GLAVIN: I think No. 3 has to do with someone  
22 at a grinder or at retail relying on testing of trimmings.  
23 And so if you are going to rely on that exemption, you can't  
24 have trimmings from another source, or anything from another  
25 source since you are relying on the testing of those

1 trimmings.

2 MS. KLINKHAMER: Okay, thank you. And I have a  
3 very basic question. If you could explain to me the process  
4 of condemning the product. Is it held in storage, is it  
5 guarded, you know, is it under FSIS control, is it  
6 discolored so that it won't be used?

7 DR. MINA: I'll address the handling of condemned  
8 product in general. Normally, that product is disposed of  
9 under the direct supervision of the inspector. And it is  
10 normally decharacterized or denatured to make sure that it  
11 cannot be used for human food. And it is either disposed by  
12 or is removed through a rendering company or is rendered on  
13 the premises.

14 MR. BILLY: How is it isolated in the plant, say,  
15 in a --

16 DR. MINA: Yeah. Well, these products are  
17 retained, meaning they apply a tag, the inspector will apply  
18 a tag, or put it under seal in a retaining cage until that  
19 carcass is disposed of. And I said, it is under the direct  
20 supervision of an inspector. We do have very tight controls  
21 on condemned product to make sure that they are disposed of  
22 properly.

23 MS. KLINKHAMER: I wanted to also ask you, when I  
24 read the directive it seemed to me that the inspectors are  
25 taking the samples within the processing plants, but

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1 compliance officers were taking the samples at retail. Is  
2 that correct?

3 MS. GLAVIN: Yes.

4 MS. KLINKHAMER: Okay. And just to confirm, this  
5 directive does cover the -- it covers retail product and  
6 product that is intended for retail, right? Okay. Now I  
7 have the Q and A questions. Can I continue, or do you want  
8 me to --

9 MR. BILLY: Have at it.

10 MS. KLINKHAMER: Okay. Under question No. 1, the  
11 very bottom of the answer, it says, "Only the product units  
12 that are represented by the positive sample will be  
13 considered contaminated." Could you please define what the  
14 product unit is?

15 DR. ENGELJOHN: This is Dan Engeljohn with FSIS.  
16 The qualification for question No. 1 starts out with this  
17 being product at a receiving establishment. So at that  
18 receiving establishment, there would have been some  
19 declaration as to what the lot for that particular sample  
20 represented. So if there were four combo bins that  
21 represented a sample of product that was positive, then it  
22 would be those four combo bins affected.

23 So again, the question sets this up as being  
24 product that is being delivered at another location other  
25 than where it was slaughtered and broken down into the

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1 various combo bins. So there are defined segments of  
2 product at the receiving establishment.

3 MS. KLINKHAMER: Okay. Now under section -- I'm  
4 sorry, question No. 3, at the end it says, "In addition, the  
5 remaining eight combos would be sampled and tested in order  
6 to determine if the 0157:H7 is present." Who would do the  
7 testing in this instance? Would it be FSIS or the plant?

8 DR. ENGELJOHN: Again, in this -- this is Dan  
9 Engeljohn again. In this situation, question No. 3 was set  
10 up as a receiving establishment would be doing the sampling.  
11 This is not of ground beef but of manufacturing trimmings or  
12 something other than ground beef. So it would be the  
13 establishment.

14 MS. KLINKHAMER: Okay. I think I know the answer  
15 to this, but I just wanted to make sure by asking you. Is  
16 the industry or are the labs testing for 0157 required to  
17 notify FSIS of positive samples?

18 DR. ENGELJOHN: I think we answered that in one of  
19 the questions. It must be question -- No. 14 was about  
20 notification of a positive sample. And if it is the  
21 industry sampling or a laboratory sampling, there is no  
22 regulatory requirement to notify FSIS.

23 MS. KLINKHAMER: Okay. And No. 5, FSIS does not  
24 intend to attempt to trace back the product or to take any  
25 regulatory action of supplying establishment that shipped

1 0157:H7 contaminated product unless there is reason to  
2 believe that the supplying establishment knew that the  
3 product was contaminated and did not have in place and  
4 followed the controls necessary to prevent adulterated  
5 product from being distributed to consumers. How would you  
6 establish intent?

7 DR. ENGELJOHN: The issue here -- again this is  
8 Dan Engeljohn -- is that we are aware of situations where a  
9 supplying establishment has worked out an agreement with a  
10 receiving establishment in that a sample is pulled at the  
11 supplying establishment and sent off to a laboratory to be  
12 analyzed. Those results may not be known until that product  
13 arrives at the receiving establishment.

14 In that case, the status of that product is  
15 unknown until it arrives at the receiving establishment, so  
16 the question that was posed in the original set of questions  
17 that we issued shortly after the January 19 issuance of this  
18 policy was that in that particular situation, is the  
19 supplier shipping product that in fact turned out to be  
20 positive. And the answer was that they didn't know that it  
21 was positive until it arrived at the receiving  
22 establishment.

23 So that would be a situation where the status of  
24 it is not known until the lab results come back in. It  
25 would be a different situation if in fact that product was



1 knowingly identified as positive. There may be records in  
2 the plant that it was positive, and they shipped it to be  
3 ground as opposed to being handled as intact product. And I  
4 think that is a situation we would have to deal with on a  
5 case by case basis.

6 MS. KLINKHAMER: Okay. For question No. 7, I have  
7 a few questions here. How could a receiver take corrective  
8 action once they have received contaminated product?

9 DR. ENGELJOHN: Again, we didn't present that  
10 information in that we don't know all of the situations that  
11 could or should occur at a receiving establishment. But it  
12 may be that establishment doesn't have in place a purchase  
13 specification, for instance, where they are specifying  
14 pathogen testing on that particular product. One corrective  
15 action may be that that would be something that they would  
16 design into their system. But I can't answer your question  
17 specifically.

18 MS. KLINKHAMER: Okay. Does FSIS have protocols  
19 for the proper disposal of product?

20 DR. ENGELJOHN: Yes, we do. I think we answered  
21 part of that in a situation where a product is identified as  
22 being positive for 1057 and asked what would be appropriate  
23 actions that that particular establishment would take.

24 MS. KLINKHAMER: Caroline, sorry to interrupt your  
25 reading, but I recall, and I just want to verify, that you

1 once mentioned that you heard of product being disposed in a  
2 landfill.

3 MS. SMITH-DEWAAL: We had discussions about what  
4 would be appropriate disposal for E. coli 0157:H7 tainted  
5 meat, I believe at one of the public meetings that Dell  
6 Allen was at. And I think that I mentioned that that would  
7 be inappropriate to dispose of it there. And actually, I  
8 think some companies have mentioned to me that that is one  
9 of their options when they face that situation.

10 MS. KLINKHAMER: Is that an option?

11 MR. ALLEN: Could you repeat -- I didn't hear what  
12 would be appropriate or inappropriate.

13 MS. KLINKHAMER: The initial question was whether  
14 FSIS had protocols for the proper disposal of E. coli  
15 contaminated product. And I had heard a comment at another  
16 meeting from Caroline about disposal of E. coli contaminated  
17 product in landfill and a concern about that disposal  
18 method. And I was wondering if that was a disposal method  
19 that FSIS approved of or had a policy on.

20 MS. GLAVIN: We do not have a policy on disposing  
21 of product in landfills. When the product is condemned, it  
22 has to be diverted from human food channels.

23 MS. KLINKHAMER: Okay.

24 MS. MUCKLOW: May I also clarify that when product  
25 goes to a landfill, it would be denatured. You can't go and

1 dig it up again and eat it.

2 MS. SMITH-DEWAAL: But that's not the point. Just  
3 for clarification, that is not the problem, Rosemary. There  
4 are many outbreaks linked to 0157:H7 from tainted water.  
5 And the question is how 0157:H7 might get into the  
6 environment. So putting tainted raw meat into a land fill  
7 where it could grow and then cause further problems  
8 downstream would be an issue.

9 MS. KLINKHAMER: And just for the record, STOP  
10 does have members who contracted E. coli 0157:H7 from well  
11 water, so that is a concern. With regard to question No. 8,  
12 you say, "Appropriate action would include the following:  
13 number one, performing appropriate corrective action." And  
14 I just would appreciate if you could give me some examples  
15 of that type of action.

16 DR. ENGELJOHN: I'm sorry, Heather. I didn't  
17 catch the question.

18 MS. KLINKHAMER: Oh, that's okay. For question  
19 No. 8, the answer is, "Appropriate action would include the  
20 following: number one, performing appropriate corrective  
21 action before reassessing a HACCP plan." And I am asking if  
22 you could give me some examples of corrective action in this  
23 instance.

24 DR. ENGELJOHN: Again, this is Dan Engeljohn. In  
25 response, we didn't identify specific things that could be

1     done. But this was a situation where the plant may not have  
2     a sample -- may have a sampling program, but it may be a  
3     rather loose program where they don't test routinely but  
4     maybe on occasion. And it could just be that this product  
5     was not tested, and that would be one thing that they could  
6     look at, again reassessing maybe the purchase specifications  
7     that they would have in place from the supplier of this  
8     product.

9             MS. KLINKHAMER: Okay. Thank you. For question  
10    No. 9, "At this time FSIS does not have specific regulations  
11    regarding the control and handling of product that has  
12    tested positive for 0157. It does have general procedures  
13    for handling the movement of product between official  
14    establishments." Could you please describe those  
15    procedures?

16            MS. KLINKHAMER: The answer to No. 9 is also sort  
17    of contained within one of the scenarios presented in the  
18    answer to No. 13. Part of that corrective action or that  
19    control that may be in place would be that if in fact a  
20    manufacturer of raw ground beef does not have in place -- or  
21    does not have access to cooking facilities and would want to  
22    make this product ready to eat, they may in fact work out a  
23    method of transferring this product between two official  
24    establishments so that the second establishment would in  
25    fact fully cook that product so that everything could be

1 distributed into commerce.

2 And so one control procedure may be that it could  
3 be identified for further processing, and that they have in  
4 place procedures to ensure that that other federal  
5 establishment would in fact be able to process all that  
6 product and account for it.

7 MS. KLINKHAMER: Earlier you had mentioned that E.  
8 coli 0157:H7 contaminated product, if it was to be  
9 condemned, would be under an inspector's supervision. In  
10 the case where it is going to be sent to another  
11 establishment for further processing, is it under an  
12 inspector's supervision during the transfer period?

13 DR. ENGELJOHN: In that particular situation that  
14 you just presented, the product is not deemed adulterated  
15 because it is going to be further processed to be made ready  
16 to eat. And so it is in fact not adulterated product. It  
17 is contaminated, but it is under control to be processed.

18 MS. KLINKHAMER: And is there any special marking  
19 or labeling on that product so if it got lost you could  
20 identify it as something that has been identified as  
21 contaminated with 0157?

22 DR. ENGELJOHN: Again, this is Dan Engeljohn. The  
23 procedures that we would have in place would be the control  
24 between those establishments, what they would work out. We  
25 don't have regulations that would require special labeling

1 on that.

2 MS. KLINKHAMER: Okay. Thank you. I have a  
3 question with regard to No. 7. I was wondering if you have  
4 any data regarding whether this type of product could absorb  
5 E. coli 0157:H7 or other E. coli along with the marinade.

6 (Pause)

7 DR. ENGELJOHN: I'm sorry, Heather. I am having  
8 difficulty hearing your question. What is the question?

9 MS. KLINKHAMER: Question No. 12 is regarding a  
10 beef cut that has been marinated. And the answer was that  
11 as long as the surface of the beef was not scored, the  
12 product would be considered intact. And what I wondering is  
13 whether there is any science or data regarding whether E.  
14 coli organisms are absorbed by a beef product like this that  
15 has not been scored, if the organism can work its way into  
16 the product when it is in a marinade.

17 DR. ENGELJOHN: In response to your question is we  
18 would generally believe that an intact cut would have the  
19 surface in place such that there would not be the  
20 opportunity for the organism to transfer from the exterior  
21 to the interior, that that surface that is not cut would in  
22 fact prevent that from happening, or it would only be at the  
23 exterior surface. So product that simply was marinated, in  
24 which it is just coated with it or is sitting in a solution  
25 of that, would not present an opportunity for the organism

1 to transfer into the interior of that normally sterile  
2 product.

3 MS. KLINKHAMER: Okay. With regard to question 13  
4 -- this is with what procedures should an establishment  
5 implement if it wants to further process beef that is  
6 contaminated with E. coli 0157:H7, in scenario B. These are  
7 briskets with corning solution, and then there is a purchase  
8 specification that has been negotiated with the specific  
9 retail outlets specifying that the corned briskets in the  
10 retail ready package will be either sold in the packaging or  
11 returned to the official establishment at the end of their  
12 use by date.

13 The retail outlet, is this a restaurant or a  
14 grocery store? Is that what you intended by retail outlet?

15 DR. ENGELJOHN: It certainly could be an option,  
16 having either a restaurant or a super market.

17 MS. KLINKHAMER: I just -- sorry to be repetitive,  
18 but I just want to make sure I understand. And so in this  
19 instance, the agreement between the retail outlet and the  
20 establishment providing these products, that agreement would  
21 be the oversight over the handling of these products. The  
22 FSIS would not be involved in oversight. Is that correct?

23 DR. ENGELJOHN: That's true. We would not  
24 necessarily be involved in that oversight.

25 MS. KLINKHAMER: Okay. I'm done. Thank you very

1 much.

2 MR. BILLY: Oh, you are very welcome. The next  
3 speaker is Nancy Donley.

4 MS. DONLEY: Thank you. Nancy Donley from STOP.  
5 I think I can safely say that we all agree in this room that  
6 E. coli 0157:H7 is something that must be addressed at all  
7 stages along the food chain, starting at and including the  
8 farm. So in that spirit, I urge the National Cattlemen's  
9 Beef Association to resurrect their on-farm research  
10 projects that they shelved earlier.

11 I also want to say that we believe that carcasses  
12 are a logical place to be testing for 0157:H7, but that they  
13 are not the only place that it should be looked for and  
14 looked at. So we think that that is again a good starting  
15 point, or a continuation, I should say, because I hope the  
16 first part is going to be done on the farm, and that we put  
17 in place a carcass testing program.

18 Major quick service establishments are requiring  
19 multi-tests, even though they retain control of their  
20 product through the final end product that winds up in the  
21 consumers' hands and in their mouths. And if they see it as  
22 something necessary to go back to their suppliers and say,  
23 look, we want to have testing done at multiple points and at  
24 multiple -- and under strict guidance and rules, I say that  
25 I think that we should all be able to expect that same level



1 of protection in the food that we buy in our grocery stores  
2 as well.

3 It is a sad day if we ever get to the point where  
4 we can say, you know, you are safe to eat a hamburger at a  
5 fast food establishment, but I wouldn't trust it out of your  
6 own refrigerator or cooking it in your own home. I hate to  
7 see that day. And I think I'm really urging that FSIS take  
8 the course that we will have an equal level of protection  
9 for all consumers, that I can see where a problem with some  
10 of the things we heard about today will -- where we could  
11 conceivably have less safe product.

12 I think we do have less safe product in some  
13 instances in supermarkets today, and that we don't let the  
14 -- I can rattle off a list of names of victims in our  
15 organization, including my own son, who became victims, fell  
16 victim to contaminated meat through grocery store outlets as  
17 well, where those supplier contracts may not be demanding  
18 such a high testing regime for product.

19 We are also asking consumers in a sense to test  
20 product as well. And in that sense, I mean that we are now  
21 -- our mantra at STOP, and I know FSIS has all their printed  
22 documents say use a meat thermometer, make sure it reaches  
23 an internal temperature of 160 degrees. So we are asking  
24 consumers as well to conduct tests, if you will, to test  
25 their food to make sure it is safe before they eat it.

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1           So in that, just to kind of recap, is that the  
2   implementation of any one of these strategies that I have  
3   mentioned on the farm, on the carcass, in trimmings, in  
4   final product, in cooked product -- not any one of those  
5   alone is good enough. We need to be doing it all if we are  
6   really committed to making meat safer. And so in that  
7   spirit again, I would like to urge FSIS to continue its  
8   course of action that it is taking on this. And again, I  
9   would like to thank you, Mr. Donley, and your agency for  
10  really being very proactive.

11           MR. BILLY: Bernie Shire.

12           MR. SHIRE: Good afternoon. Bernie Shire from  
13  American Association of Meat Processors. My presentation is  
14  going to be more in the form of some questions, like a few  
15  other people here, and not necessarily to be answered this  
16  afternoon, but some things to think about.

17           The American Association of Meat Processors  
18  represents a large part of the small meat industry. We have  
19  1,800 members; 1,500 of them are meat plant operators. They  
20  are involved in all phases of the meat business. Some of  
21  them make one product, some make dozens of products. Some  
22  slaughter one species of animal, other several species.  
23  Others do nothing but grind beef. Others still make the  
24  bulk of their living from ready to eat products. Still  
25  others do a little bit of everything. They have their feet

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1 virtually in all the camps.

2 They all have one thing in common, though, whether  
3 they are slaughtering or processing or dealing in non-intact  
4 products. The quality they all share is that whatever they  
5 do, they do it on a small scale. I mention that because I  
6 have listened to the proposal that the big packers have  
7 posed, and some of those proposals sound very promising.  
8 But the discussion also raises a lot of questions, questions  
9 that I hope will be answered over the next few weeks.

10 How will this proposal affect small slaughterers  
11 as well as the big packers? What responsibility will the  
12 ranchers and the farmers have in this matter? It has been  
13 proposed as a voluntary program. What happens to  
14 slaughterers and others that don't get involved, for  
15 whatever reason? Will their product be considered not as  
16 good? Is there a danger of a two tier system being set up  
17 at some point down the road, a two tier system for  
18 inspection?

19 I was in a small slaughter facility recently where  
20 they killed one animal at a time, ten a day, only two days a  
21 week. They do a very fine, clean job. And part of that, I  
22 guess, is because they don't have to deal with the numbers  
23 and other problems that arise in large slaughter plants.  
24 They may only have one intervention set up. It seems to  
25 take care of everything. If the proposal as outlined goes

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1 through, will these small folks need to go to three or four  
2 interventions as well to keep up? What if they don't? Will  
3 they be discriminated against? And then what next? What  
4 will the next step be down the regulatory road?

5 Months ago -- I can't see the last part. I guess  
6 the last thing I would say is that we hope the agency will  
7 extend the comment period for a few more weeks. Our meat  
8 inspection committee would like the opportunity to examine  
9 more closely what is being discussed, as well as any other  
10 changes that may be made, to determine how it will affect  
11 all of our members and others in the small meat industry.

12 Thank you.

13 MR. BILLY: The last person that is on the list is  
14 Caroline Smith-Dewaal.

15 MS. SMITH-DEWAAL: Thank you, Tom. It is Caroline  
16 Smith-Dewaal, with the Center for Science in the Public  
17 Interest. I do want to thank you for holding this meeting  
18 and airing many views. This is a bit of a different kind of  
19 a meeting because we are used to coming in and having, like,  
20 a whole morning of the agency presenting its policy, and  
21 then the rest of us responding. And today I felt like we  
22 came in and the industry presented its alternative or idea  
23 for dealing with it, and then there were a lot of questions  
24 left over for some people on how the actual policy would  
25 work.

1           I do want to say on behalf of CSPI's one million  
2 members that we support the clarification of E. coli 0157:H7  
3 policy. And I think that what -- it is exciting, the kind  
4 of innovation and the ideas which are now being tossed  
5 around about how to really get a better handle on  
6 controlling E. coli 0157:H7 in the pipeline before it gets  
7 to the retail, before it gets to the further processor. So  
8 I am very excited to hear about the carcass sampling ideas  
9 that have been put forward by the largest slaughter  
10 operations and the pilot testing which they are agreeing to  
11 do. These are all very, very positive things.

12           I think the problem comes with the carrots. And  
13 if it weren't so serious, I would kind of think about my  
14 kids, who are always saying, well, if I clean my room, what  
15 will I get, you know. It is like, well, you'll get a clean  
16 room. Well, that is not necessarily -- they want to know if  
17 they'll get their allowance or they'll get something else if  
18 they do the right thing.

19           The reality is that what E. coli 0157:H7 is  
20 forcing -- there is a lot of uncertainty. And the question  
21 is should the uncertainty be on the fast food restaurants,  
22 should the uncertainty be on the meat packers, should it be  
23 on the cattlemen, should it be on the consumer. Where  
24 should that uncertainty lie? And you, Tom, are the pivotal  
25 point to make that decision. And so everyone is saying,

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1 well, don't leave us holding the bag, leave someone else,  
2 put the uncertainty somewhere else.

3 When I look at Dell's map -- and I thought the  
4 presentations today were just excellent from the industry.  
5 But when I look at Dell's map of where his product went, I  
6 think also back to many maps I have seen at presentations by  
7 CDC on where the outbreak was. And as we see these products  
8 being transported incredibly quickly all over the country,  
9 that is what the outbreaks look like. And in addition, it  
10 is what the recalls, the nightmare of a recall, looks like.  
11 And so I just want to say to the industry, the carrot is  
12 that the recall nightmare should be lower.

13 If you do the carcass sampling proposal that you  
14 have put together, you should see fewer recalls, fewer  
15 positive 0157:H7's in the marketplace. It should be --  
16 you'll get a cleaner room. I know that doesn't -- it never  
17 works with the people I am dealing with. But what you are  
18 proposing is a good idea, regardless of what the agency  
19 gives you as a carrot, if anything.

20 I think there is some confusion that I have heard  
21 today about the role of the government, and this issue of,  
22 you know, less -- we want more prevention from the  
23 government and less punishment. Well, the reality is the  
24 prevention is within the hands of the industry. It is not  
25 the government's job to prevent the problem. And so I don't

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1 see your programs as punitive. I see your programs as  
2 designed to try to get the industry to address a problem.

3 I also strongly believe as a result of the  
4 discussions today the industry testing isn't a substitute  
5 for government testing. And so don't fall in that trap,  
6 saying, well, they are testing, so we don't need to, and  
7 making that trade. I don't think that is a fair trade.  
8 Consumers want multiple hurdles. We want both the industry  
9 testing and the government testing. That is a multiple  
10 hurdle approach.

11 But all of that said, I do support incentive based  
12 regulation. And what the industry has come forward with  
13 today is a system saying, you know, gosh, if you could make  
14 these clarifications and these changes, we'll do more  
15 testing, and we want more testing. I would like to suggest  
16 some improvements to what we have discussed today in terms  
17 of the carcass sampling proposal. I like the clarification  
18 where it says -- can I borrow the regulation? And I'll be  
19 brief, I hope. Thank you.

20 I liked the clarification where it changes the  
21 language of 4(b)(3) to instead of saying routinely verify  
22 the intervention's effectiveness periodically through  
23 testing, but where it says through carcass sampling. It  
24 should be verification through carcass sampling. I think  
25 that gives greater clarification to this policy.

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1           I made my point on the validation versus  
2 verification issue. I think that is already in the record.  
3 And I also -- I would like to make one addition to what has  
4 been proposed today, and that is I think in the issue of  
5 certainty, in the issue of not leaving consumers holding the  
6 bag with this change, on the issue of a fair policy for  
7 consumers, the department should consider the issue of lot  
8 size.

9           If you are going to give an exemption to testing  
10 not only to the specific slaughterer or processor, all the  
11 way down to retail -- if you are going to give that kind of  
12 -- if you are going to have that kind of carrot for the  
13 industry, I think you really need to look at lot size. What  
14 the industry is saying is we're going to sample 1 out of  
15 every 300 carcasses. And I think in that case, the lot size  
16 should be from the point of the last negative result to the  
17 point of the next negative result because that positive  
18 result, that single carcass that is positive for 0157:H7  
19 shows that the interventions, the multiple hurdles in use in  
20 that plant, were not working.

21           And so if you had a lot size that encompassed from  
22 the last negative to the next negative, you would encompass  
23 the period during which the interventions, the process, was  
24 out of control. And we don't know how many of those  
25 carcasses went by that were positive for 0157:H7. But I



1 believe a policy like that, even if the sampling frequency  
2 was a minimum frequency of 1 in every 300, it would  
3 encourage more sampling. It would encourage the industry  
4 because then you could reduce the lot size. And it would  
5 encourage faster testing technologies. They would want to  
6 get tests that were less than 24 hours as soon as they  
7 became available.

8 I think that that kind of a change would provide  
9 much greater certainty for consumers, that this policy  
10 actually will serve consumers' interests as well as  
11 industry's. Thank you.

12 MR. BILLY: Thank you. Well, I would like to --  
13 I'm going to open it up for comments generally, both to the  
14 most recent comments as well as any other comments that  
15 anyone might like to raise at this time. We'll start with  
16 Dell.

17 MR. ALLEN: I'd like to address Caroline's last  
18 point. I assure you, as I have said before, if it were  
19 physically possible, technologically possible, I would not  
20 argue with some of the things you are saying. So I just  
21 today -- and this is sharing data, okay -- had a return on  
22 it. We are testing carcasses. And when we test a carcass,  
23 we isolate the carcass, and that begins by isolating it all  
24 the way through the chain so that we don't have cross-  
25 contamination possible.

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1           But anyway, carcass slaughtered last Monday, okay,  
2 one week ago today, March 1 -- the tests went in as I have  
3 indicated before, via air express. Sometime last week, and  
4 it was either Wednesday or Thursday, we got the word back  
5 that it was a presumptive positive. So the next step is  
6 taken. You go through the confirmed negative step. I got  
7 those results today, just about an hour ago. If I have that  
8 situation in a lot of 300 carcasses, this deal is dead on  
9 arrival because my people -- and I am talking -- we cannot  
10 afford to have the space. There is no way on God's green  
11 earth that we can hold that many carcasses for that length  
12 of time.

13           So until and unless we have some of these testing  
14 methods that are more rapid and more readily done, what you  
15 are suggesting just will kill this thing before we ever get  
16 it off the ground.

17           MS. RICE: Kim Rice, AMI. I want to address  
18 something Bernie said and something Caroline said. And it  
19 goes to the issue of large versus small. I just wanted to  
20 clarify that there were both large and small processors and  
21 packers who participated in this coalition and came up with  
22 these recommendations. So this is not large packers  
23 bringing something to the table that the small could not.  
24 And it has been a discussion all along: make sure we still  
25 provide opportunities for the small people to participate in

1 the directive 10010. And anybody else on the coalition who  
2 wants to talk to that can.

3 MR. BILLY: Marty.

4 MR. HOLMES: I would confirm with Ken what I said  
5 in those meetings, and more than once I heard the large  
6 packers say wait a second, we have got to make sure this is  
7 workable for the small packers as well. That is not my  
8 point, though.

9 My question is actually for Caroline. I heard you  
10 say that you were in support of the USDA's clarification  
11 policy. I see their policy as two separate issues, one on  
12 trimmings of ground beef and testing of carcasses, which has  
13 been proposed here, the other being mechanically tenderized  
14 products. And I just wanted to clarify whether you agree  
15 with the thing in full or if you see clarifying with part of  
16 the issue.

17 MS. SMITH-DEWAAL: Thank you for your question.  
18 It is Caroline Smith-Dewaal. I'm going to have to look at  
19 the Kansas State data. We haven't fully -- I mean, I think  
20 the issue of needle tenderizing needs to be considered by  
21 this industry in light of 0157:H7. I think some of the  
22 data, though, that I saw for the first time today was  
23 certainly interesting and may inform us as we move forward  
24 in writing our comments.

25 MR. BILLY: Carol.

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1 MS. TUCKER-FOREMAN: Carol Tucker-Foreman again.  
2 Could we have a little discussion involving the FSIS people  
3 about the point that Dell just made in response to Caroline  
4 about the carcass testing and the numbers and how we deal  
5 with this problem of isolating every carcass that is tested?  
6 I would like to get your response on that.

7 MS. GLAVIN: What is your question, Carol? How  
8 should we handle those carcasses?

9 MS. TUCKER-FOREMAN: Dell says everybody, when  
10 they test a carcass, they isolate it. Therefore, they are  
11 reluctant to test more carcasses because it is holding more  
12 meat. If they don't isolate it, you are obviously exposed  
13 for all of that product in the plant.

14 MS. GLAVIN: I think what Dell was talking about  
15 was not necessarily that if you test more you have to hold  
16 more, but it was responding to Caroline saying that every  
17 one you test stands for 300 in this proposal, which means  
18 that all of your production, every single thing you produce,  
19 is held until you have test results. And I think that is  
20 what he was reacting to.

21 MS. TUCKER-FOREMAN: No. Caroline, is that what  
22 you were suggesting?

23 MS. SMITH-DEWAAL: No. It is not that everything  
24 was held. It is that you would release lots as you got two  
25 negative tests. From negative test -- you are testing 1 in

1 every 300 cattle, carcasses. So your test would have -- you  
2 would move through 300 at a time. Where you got a positive,  
3 though, it would implicate meat on both sides. It would  
4 actually be 599 carcasses.

5 But understand, these carcasses go into a cooler  
6 for anywhere between 24 and 36 or even more hours. And  
7 testing technology is available where if you have enrichment  
8 you can get a presumptive positive or negative back within  
9 about 24 hours. Now there is a problem Dell has with  
10 mailing the carcass -- or mailing the samples from Texas  
11 somewhere. So I understand that.

12 But what we are doing here -- Dell today is  
13 dealing with a problem where he -- the policy now would  
14 require him to recall 200 million pounds of meat or  
15 2 million pounds of meat a day from that plant from clean-up  
16 to clean-up. Or it is some huge amount of meat that is  
17 implicated. Here we are saying it is a much smaller amount  
18 of meat. We are talking about 599 carcasses versus 4,000  
19 carcasses.

20 So it is essentially -- it certainly gives us much  
21 greater certainty. And otherwise, what Ann Hollingsworth  
22 has been suggesting is that you are just going to run this 1  
23 every 300 until there is an outbreak. And as soon as there  
24 is an outbreak and your product is implicated, then gosh,  
25 you are going to take all kinds of control measures. But

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1     what that does is that leaves consumers holding the bag.

2             MR. ALLEN: I would defer to some of the  
3     microbiologists here in terms of the number of presumptive  
4     positives that occur that end up being negative. My  
5     experience is they are considerable. I cannot -- I'll  
6     emphasize it again. If I go back to my people who run my  
7     operations and tell them we have got to hold 300 -- now you  
8     have got it to 600 -- carcasses from Monday last March 1 to  
9     this day, they are going to look at me and say we're much  
10    better off not even knowing, so let's don't even test. That  
11    is going to be the reaction of about anybody that faces that  
12    kind of a situation.

13            MS. SMITH-DEWAAL: But it also creates an  
14    incentive, Dell, for you to test more frequently.

15            MR. ALLEN: Yeah. But I can't. I have already  
16    told you that I can't, physically cannot do that.

17            MS. TUCKER-FOREMAN: It is Carol again. Is the  
18    problem that it takes you too long to get the test results  
19    back? Are you holding for so long because you have to get  
20    those test results back?

21            MR. ALLEN: That is exactly right. Once we test,  
22    we will not release whatever is tested until we get the test  
23    results back.

24            MS. TUCKER-FOREMAN: Dell, this goes back to who  
25    ends up having to -- I hate to use the term "hold the bag"

1 on this. We would like to keep the pressure on you to  
2 create a technology that gets you those answers a lot faster  
3 rather than create a system that is dependent on less  
4 testing. You have much more influence in order to be able  
5 to drive that technology. And if you remove that pressure  
6 to drive the technology, you'll never be able to do more  
7 testing.

8 MR. ALLEN: That pressure is there and will not go  
9 away, I assure you.

10 MS. TUCKER-FOREMAN: I think your proposal, which  
11 I find very interesting and, you know, I would like to find  
12 a way to be more positive about it, is -- one of the things  
13 that just keeps coming back to me is it removes the pressure  
14 to drive the testing technology forward as quickly as I  
15 think that it has to go forward.

16 DR. HOLLINGSWORTH: Ann Hollingsworth, Keystone  
17 Foods. The pressure for increased testing, regardless of  
18 what happens here, is not going to go away. There are a lot  
19 of dollars to be made to the person or group of people who  
20 develop the testing that can give us more rapid answers.  
21 There are, as Dell alluded to earlier, those of us that are  
22 in positions like his position, my position, and many of the  
23 rest of the guys on this side of the table at least,  
24 probably most of us around this room.

25 We get people that have a new test that is going

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1 to give us everything we want to know at least once a week  
2 and many times multiple times in a week. It takes time to  
3 develop those tests. It takes time to verify that what we  
4 think we have got in the develop of tests will indeed do  
5 what we hope it will do. It takes a lot of what we call  
6 beta-site testing. And there are numerous machines and  
7 systems out there that are in beta-site testing protocols  
8 right now that are working towards making this kind of thing  
9 a reality.

10 I don't believe that regardless of what the agency  
11 does on E. coli 0157:H7 testing that that pressure is going  
12 away, because there is a lot of money to be made and the  
13 people that are working in that area or have the expertise  
14 to work in that area are fighting feverishly to be the first  
15 guys to cross the line.

16 DR. WACHSMUTH: I can clarify the technology  
17 question.

18 MS. TUCKER-FOREMAN: I beg your pardon?

19 DR. WACHSMUTH: I wanted to clarify the technology  
20 of the screens just to give you some context for what Dell  
21 mentioned. With our screening test for 0157:H7, we get  
22 between 20 and 25 false positives for every confirmed  
23 positive. And we have looked at things like the Qualicon  
24 and other instruments, and they have approximately the same  
25 rate. What you don't want is something faster that is going



1 to give you false negatives so that you miss something. You  
2 want to make sure you pick up everything. And the cost of  
3 picking up everything is a large number of false positives.

4 MS. TUCKER-FOREMAN: It is Carol again. I think  
5 that I at least end up being in the position of saying when  
6 you get the technology to do more tests, then we can talk  
7 about what you are proposing. And it is hard to talk about  
8 it when it is just 1 in 300, and we clearly feel very  
9 uncomfortable about it.

10 MR. DANIALSON: Carol and Caroline, just a couple  
11 of responses, the holding the bag issue, who is holding the  
12 bag. I don't think that we can -- I mean, I will emphasize  
13 that, you know, I mean, putting the validated interventions  
14 into this bag, the policy bag, is the key element here. If  
15 we were just sitting over here and saying, let's just go to  
16 this carcass testing program and we don't need these  
17 interventions, you don't need the HACCP process, I think,  
18 you know, you could legitimately question that we are losing  
19 something here.

20 The interventions and the validated interventions  
21 in the process is key of where we have evolved over the last  
22 few years. You say we are reducing frequency. Well, the  
23 pilot will tell us that. One in 300 sounds like a lot. If  
24 I have one of my beef plants 1 in 300, that is about once an  
25 hour, where today that plant is getting sampled four times a

1 year by USDA. One in 300 sounds a lot in -- or doesn't  
2 sound like much. In reality, it is a lot of sampling, and  
3 it is a lot of surveillance that is being conducted in these  
4 plants in association with the interventions that are  
5 coupled with them.

6 MR. HOUISKEN: Rod Houisken, Houisken Meats. I  
7 believe everybody in this room is doing the very best that  
8 they can do to help with this problem, from industry with a  
9 lot of innovative ideas, the USDA, as well as the consumer  
10 groups here. We have a very tough problem. But there is  
11 one thing that we can do, each one of us, to help eliminate  
12 the illnesses from E. coli 0157:H7. I would like to talk  
13 about that in just a second.

14 As I travel around the country, when I go to a  
15 restaurant or when I visit homes, I will ask for a hamburger  
16 and ask if I can have it rare. And in about eight cases out  
17 of ten, the waitress will say sure, we serve it your way.  
18 And I say, aren't you worried about E. coli? And she says  
19 no, my product has been tested.

20 Okay. What can we do to help solve this problem?  
21 Many of you people here are in front of public television or  
22 radio quite often. And I would like to put out a challenge  
23 to the consumer groups, to the USDA, anybody that has a  
24 voice, when you talk about this problem, there is one sure  
25 and easy way to solve it. In addition to what we are all

1 doing in this room, the housewife needs to fully cook the  
2 patty. And that message needs to get through. So I  
3 challenge each one of you, when you have the opportunity,  
4 speak about fully cooking your patties. Thank you.

5 MR. MROZINSKI: I would like to -- my name is Pete  
6 Mrozinski, and I with Qualicon. And I just want to make a  
7 couple of statements. There has been a lot of talk about  
8 false positives and confirmed negatives. And I am not a  
9 microbiologist, but I have been working in this area using  
10 DNA methods for detecting E. coli. And I think the term  
11 "confirm negative," first of all, is misleading. You cannot  
12 confirm a negative, especially for this organism. The  
13 standard methods for confirmation are not adequate to either  
14 confirm a positive or a negative.

15 There are DNA methods available today that can  
16 specifically find the organism at very low levels in ground  
17 beef or in any beef. The term "false positive" is another  
18 term that has been used a lot. And when you are talking  
19 about a screening method in microbiology, a false positive  
20 is defined traditionally as a positive that the screening  
21 method finds that your standard method does not find. That  
22 can't really hold in this case because the standard methods  
23 are not good enough to find the organism.

24 So you need to think of a false positive as a  
25 known interaction, a known failure of the test. And with

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1 many screening tests, there are known failures, there are  
2 known cross-reactivities. And that is a real false  
3 positive. With genetic tests that can be tuned to the  
4 organism specifically, we know that we can get tests that do  
5 not cross react with other organisms and therefore do not  
6 produce false positives. But they also cannot be confirmed  
7 culturally, but that is a failure of the culture method, a  
8 failure of the confirmation, not a failure of the screening  
9 test.

10 So there is a lot of talk about false positives  
11 and confirmed negatives that I think get confused a lot,  
12 especially when you are talking about this organism in  
13 particular because it is very difficult with standard  
14 methods to culturally isolate. Thank you.

15 MR. BILLY: Phil.

16 MR. OLSSON: Thank you. I would like to address  
17 -- Phil Olsson of Olsson, Frank & Weeda. I would like to  
18 address Carol Tucker-Foreman's comment regarding more rapid  
19 test methods. And I think there are a number of people who  
20 share the desire to see more rapid test methods. I was  
21 speaking earlier with Nancy Donley, speaking about a desire  
22 for real time test methods.

23 But I don't think it is entirely up to the Dell  
24 Allens of the world to get there. And the reason I say that  
25 is that if you would look on the ARS Web site right now, you

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1 would find that they identify a new test method for E. coli  
2 0157:H7 with a six hour turnaround that is 10 to 100 times  
3 more sensitive than what is available.

4 This was introduced to the industry at a meeting  
5 two or three weeks ago in California with a caveat from an  
6 FSIS official that it would need to be enriched. And so  
7 don't look at six hours, look at 24 hours. So suddenly you  
8 are getting back into the very problem that Dell Allen  
9 describes, which is that if you have got a six hour machine,  
10 you buy it, you make the test right at the packing plant.  
11 If you have got a 24 hour process and enrichment, you send  
12 it out, and you get a three or four day process, and that is  
13 what backs him up, the point being that this is an area like  
14 so much of what is going on here that we need cooperation.

15 And I think -- I mean, you are as cooperative as  
16 anyone. I'm not, you know -- we are not on opposite sides  
17 of this issue. But I think there is a lot of potential in  
18 all of us working with the agency to get better test  
19 methods. Industry only wants to use test methods that are  
20 being used by the agency because you want to do the same  
21 thing they are doing. Thank you.

22 MR. BILLY: Rosemary.

23 MS. MUCKLOW: Tom, Phil is absolutely right. And  
24 new and better test methods are going to be welcomed. Even  
25 as we sit here today, there are people researching, out

1     there doing some field tests on new interventions. This  
2     industry is looking in a very fertile way to try to solve  
3     this problem. They recognize it is a problem. The Beef  
4     Industry Food Safety Council Consortium has been looking at  
5     it and doing a lot of stuff to try to address the issue.

6             I did want to raise a point that I didn't mention  
7     earlier on, and that is it is like a shoe shop. No one size  
8     fits everybody. And Kim Rice has talked a little bit about  
9     there being involvement of some of the smaller firms in this  
10    effort to come to you today and to suggest truly that there  
11    is going to be a great deal more testing and more  
12    information to give us a better handle on looking for this  
13    microorganism.

14            I would urge you that we also need to remember  
15    some people that I once upon a time forgot, and they  
16    reminded us when they came to the Michael Taylor six day  
17    meetings, and that is some of the ethnic slaughterers, halal  
18    and kosher. They don't like interventions at all. And so  
19    we must be very mindful of the fact that there are people  
20    who can get a carcass clean with methods other than the ones  
21    that we are talking about today, and we need to be very  
22    careful not to count them out as we sweep along with some  
23    new ideas -- a lot of ways of getting to the end of the line  
24    that are called "food safety outcomes," I think is what  
25    Dr. McKenzie from New Zealand calls them. We need to be

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1     able to determine what those food safety outcome  
2     expectations are.

3             We are talking about a lot more testing. And I  
4     could read you the statement again, but you don't want to  
5     hear it for the second time. No, I didn't think so. I  
6     haven't got the voice for it anyway. Thank you very much.

7             MR. BILLY: Yeah. We have talked about that and  
8     are aware that there are special ways of slaughtering and  
9     processing animals to meet certain religious requirements.  
10    And we will take that into account as we move forward in  
11    this. Over here.

12            MS. WHITE: My name is Jill White. I am from IGEN  
13    International, the company to which Phil Olsson referred to  
14    for the technology that FSIS just announced. And that six  
15    hour test includes the enrichment time. It takes one hour  
16    to run the test on our machine, 50 samples analyzed at one  
17    time, and the enrichment time is five hours, actually, so it  
18    is six hours total for the test.

19            MR. OLSSON: And let me point out that the slide  
20    was correctly presented. It is correctly presented on the  
21    ARS Web site. It is just that it was introduced at the  
22    industry meeting as requiring additional enrichment, even  
23    though it is already 10 to 100 times as sensitive. And I  
24    think what we are hearing today is we need 10 to 100 times  
25    as fast.

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1 MR. BILLY: Okay. Heather and then Jim.

2 MS. KLINKHAMER: I have a couple of questions  
3 about the testing. I can't remember which one of the  
4 industry representatives earlier in the meeting said that  
5 the combo purge test was not a good one. And I was hoping  
6 that whoever made that remark could explain why the purge  
7 test has been dismissed. And also, I wanted to know if  
8 anyone here has information about whether testing intact  
9 beef products would yield more results than ground products  
10 because it is my understanding that because ground products  
11 come from a larger pool and are mixed around that you are  
12 more likely to get a positive test in the ground product, if  
13 there is E. coli there.

14 MR. BEILA: Tim Beila with American Food Service.  
15 I made the comment about the purge sampling and testing.  
16 There was research published -- I don't have it here with me  
17 today -- that addresses or actually compared different types  
18 of sampling and testing methods, specifically comparing  
19 combo purged trimming and things like that. And there is no  
20 good correlation that can be established between surface  
21 sampling and testing and the purge that is collected from a  
22 combo bin.

23 To go further with that, there are some types of  
24 trimming that do not have a significant amount of purge  
25 available to sample. And again, I don't have that in front



1 of me, but if you would see me afterwards I can get you a  
2 copy.

3 MS. KLINKHAMER: Do you recall, was it a research  
4 institution or ARS?

5 MR. BEILA: It was a university research project.

6 MS. KLINKHAMER: Okay.

7 MR. BILLY: Jim.

8 MR. HODGES: Thanks, Tom. Jim Hodges, American  
9 Meat Institute. The point we have reached today has  
10 virtually taken us years to get here. It is a point where I  
11 think no one in the industry would have supported four years  
12 ago, and it is not without burden, it is not without cost.  
13 But it is something that we think is necessary to be done.  
14 It is necessary because one, it will give us more  
15 information than what we have today.

16 The American Meat Institute Foundation is  
17 initiating a very aggressive research agenda. One of those  
18 things that will be coupled, hopefully, if this moves  
19 forward -- one of those areas that we hope to couple with  
20 this carcass sampling program is to determine the incidence  
21 level of 0157 coming in on animals, whether it be on the  
22 hide, whether it be in the intestine. But we can't do that  
23 unless we have some ability with the regulatory agencies to  
24 cooperate to make this logistically possible.

25 If we don't -- if we are talking about holding 300

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1 carcasses, we are not talking about verification of an  
2 intervention system. What we are talking about is an accept  
3 or reject criteria on some defined lot. And there is not  
4 any sampling program that can be designed that is  
5 statistically valid that will accept or reject product.

6 So I am pleading with this group, both the  
7 regulatory agencies and the consumer community, that we need  
8 the ability to take a step forward. It is not where we were  
9 hoping we were going to be. It is not the solution to the  
10 problem in its entirety. But it is clearly and  
11 unequivocally a step forward. And if we start to put it in  
12 the context of being a disincentive, we are going to stay  
13 right where we are. We have got to move forward, and we  
14 need your help.

15 MR. BILLY: Caroline, and then I think we'll wrap  
16 it up.

17 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center  
18 for Science in the Public Interest. I really don't see a  
19 proposal on the lot size issue as making it an accept or  
20 reject system at all. And I really -- I think the industry  
21 has made tremendous progress here and carcass sampling is --  
22 you know, you have convinced me this is the way to go. The  
23 issue is, how do we protect consumers while we are gathering  
24 the data that will give us sufficient certainty in the  
25 carcass sampling system?

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1           And I think you have gone a tremendous way. I  
2   just don't think we are quite there yet with the certainty  
3   of the sampling proposal. So I would like -- I just wanted  
4   to be clear that what we are talking about very much is a  
5   HACCP system that chose interventions -- a positive result  
6   would show interventions are not working as well as they  
7   should be. Thank you.

8           MR. BILLY: All right. I would like to wrap this  
9   up, unless someone else has a burning comment, a burning  
10   comment.

11           (Laughter)

12           MR. BILLY: I think that notwithstanding some of  
13   the issues that have been raised, that we have reached a  
14   very important crossroads. The feel of this meeting and the  
15   ideas that have been put forth and the concerns and so forth  
16   that have been raised have a remarkable different feel to  
17   them than what at least I experienced a few years ago. I  
18   think there is a chance represented in what has been put on  
19   the table, as well as considering the issues raised. There  
20   is a chance to turn in a new direction. And I am going to  
21   do my best and have the agency do its best not to lose this  
22   opportunity.

23           The dialogue is real important. And the dialogue  
24   doesn't have to be limited to a public meeting called by  
25   FSIS. People are around, and there are phone numbers

1 available. And I think as we move forward continuing the  
2 dialogue can do a lot to help all of us collectively figure  
3 out the proper approach in this new direction.

4 The industry coalition has put a proposal, at  
5 least in an outline form, on the table. You have heard some  
6 support for it. You have heard some questions raised about  
7 it. We are prepared to provide a framework in which you  
8 have some time to consider all of this input and then to  
9 provide us in writing a more specific proposal that all of  
10 the participants and anyone else could then consider and  
11 comment on this part of this process. I think that makes a  
12 lot of sense to me and will net us a better record, a better  
13 set of comments to consider how to continue this positive  
14 direction.

15 I think that the comment period is very important,  
16 and I know that all of you here, because you are here, care  
17 about this. And I think you can provide a very valuable  
18 service in terms of public health by being an active  
19 participant in this process.

20 For some of us, it is hard to appreciate the kind  
21 of numbers that Dell Allen put up at the beginning in terms  
22 of one plant and the production from one day and what  
23 happens to that production and the logistics and the  
24 practicalities of dealing with some of these issues.

25 At the same time, it is important that we

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1 appreciate the concerns of the consumers in terms of having  
2 an approach that nets for them the best possible protection  
3 from a public health perspective. And therein, I think, is  
4 where we need to continue this process and sort out an  
5 approach that will net us the kind of movement in a new  
6 direction that this discussion today represents.

7 So I guess if I wanted to leave you with anything,  
8 it is to encourage you all to continue this dialogue, be a  
9 full participant in this process. And I think if you are,  
10 we will really achieve something here that we can all be  
11 proud of. So again, thank you very much for your  
12 participation today.

13 MS. MUCKLOW: Tom, before we go, do you understand  
14 that now there will be a request to extend the comment  
15 period? We'll get a document from -- a fuller document from  
16 the industry and you'll publish that?

17 MR. BILLY: My intent is to take the request from  
18 Bernie and other comments today as a request for a longer  
19 comment period. I heard earlier from the industry a  
20 willingness -- and they can confirm this -- to provide  
21 something in writing that would help all participants  
22 comment, if that is correct, a proposal that would put in  
23 writing what we heard about today. I believe I heard that,  
24 Kim.

25 MS. RICE: Say that again.

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1 MR. BILLY: It is a proposal that lays out the  
2 approach that was outlined here today for a pilot project  
3 that would include the various features that were put on the  
4 table and how this would all work. Is that correct?

5 MS. RICE: Yeah.

6 MR. BILLY: I see some heads shaking. I don't  
7 hear a yes.

8 MS. RICE: Yes.

9 MR. BILLY: And when would be a reasonable time  
10 for that, maybe by the original deadline?

11 MS. RICE: We'll get back to you in a couple of  
12 days.

13 MR. BILLY: Okay.

14 MS. RICE: I'll get back to you by Wednesday.

15 MR. BILLY: Yeah. I think what we'll do is make  
16 it available.

17 MS. GLAVIN: If we did it on the Web site through  
18 the constituent update, that kind of thing? Okay.

19 MR. BILLY: We'll get it available.

20 MS. GLAVIN: Putting it in the Federal Register  
21 will take us the rest of the year.

22 MS. MUCKLOW: I understand. No, no, no, no.  
23 We'll be doing this.

24 MR. BILLY: Okay. And then we'll provide an  
25 opportunity for comment. All right. Is that clear? Is

1 everyone clear on that? Any questions? Okay. Again, thank  
2 you all very much.

3 (Whereupon, at 3:30 p.m., the public hearing was  
4 adjourned.)

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Washington, DC  
Place of Hearing

March 8, 1999  
Date of Hearing

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